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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,809	02/05/2004	Joel E. Bernstein	41957-102748	5946

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
01/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/772,809	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Renee Claytor	1627	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 November 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

It is noted that the present claims have not been entered because of the addition of new claims 18-20, which limit the composition to specific ingredients that were not previously presented and would require a new search. Further, claim 11 has omitted the tricyclic compound doxepin which was presented in the claim set 4/28/2009 and claim 11 has not presently been amended.

Applicants argue over the 35 USC 102 rejection over Crawford that the goal of Crawford was an improved anti-inflammatory composition that reduced gastrointestinal irritation. Applicants further argue that the "consisting essentially of" language excludes the piroxicam and analgesics taught by Crawford. Applicants further argue that the preamble should be afforded patentable weight because those of skill in the art seeking a pain relief composition would not be directed to Crawford who does not teach pain. Applicants further argue that the dose range of the tricyclic antidepressant is not taught by Crawford.

In response to the above arguments, it is noted that the term "consisting essentially of" limits the scope of a claim to the specified materials "and those that do not materially affect the basic and novel characteristics" of the claimed invention. While Applicants believe this definition excludes piroxicam and analgesics taught by Crawford, it is noted the claim is drawn to a tricyclic antidepressant and a non-narcotic analgesic. Crawford meets this limitation by teaching piroxicam, which is a NSAID and doxepin, which is a tricyclic antidepressant. Col. 4, lines 1-7 teaches that piroxicam can be administered with doxepin; therefore, Crawford meets the claim limitation. Therefore it is not clear how the definition would exclude piroxicam. Regarding the argument considering the preamble, it is noted that was not the argument presented by the Examiner. It was pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art. If the prior art is capaable of performing the intended use, then it meets the claim. Regarding the dosage range, it is noted that Crawford teaches a treatment composition comprising 20 mg of doxepin which falls within the range in claim 9.

Applicants argue over the 35 USC 103 rejection that Caruso provides an antidepressant and an NMDA receptor antagonist to improve pain relief. Applicants assert that there is a laundry list of pharmacologically active substances which include non-narcotic analgesics that must be in combination with a NMDA antagonist. Applicants further argue that Matheson only describes rofecoxib and is not within the scope of the present invention.

In response to the above arguments, it is noted that Caruso et al. was used for the teaching that doxepin is provided in compositions in the hydrochloride form. Further, Matheson was used for the teachings that non-narcotic analgesics such as rofecoxib, ibuprofen and naproxen are used in doses that fall within the range of that in claim 17, which are considered normal doses. Therefore, the teachings of Matheson are within the scope of the present claims because it teaches the state of the art regarding doses of non-narcotic analgesics.